PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of Burbank et al.	Examiner: Not Assigned Group Art Unit: Not Assigned
For: **METHODS AND APPARATUS FOR SECURING MEDICAL INSTRUMENTS TO DESIRED LOCATIONS IN A PATIENT'S BODY**	Customer No.: 23422
Serial No.: Not Assigned Filed: December 4, 2001 Docket. No.: 9619-1011	**PRELIMINARY AMENDMENT AND INFORMATION DISCLOSURE STATEMENT**

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BOX PATENT APPLICATION
Commissioner for Patents
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

Please amend the above identified specification and claims as follow:

IN THE SPECIFICATION

On page 1, line 3, after the title, please insert the following:

This application is a divisional of copending U.S. Patent Application Serial No. 09/146,185, filed September 1, 1998, by Burbank et al., which is a continuation-in-part of copending U.S. Patent application Serial No. 09/057,303, filed April 13, 1998, by Burbank et al., which is a non-provisional application of U.S. Provisional Patent Application Serial No. 60/076,093, filed March 3, 1998, by Burbank et al., priority to which is claimed under 35 U.S.C. §§119(e) and 120 as applicable.

IN THE CLAIMS

Please cancel claims 1, 2, 12, 14, 16-18, 23, 30, 33, 34, 37, 38, 41, 42, 44, 47 and 48.

Please amend claims 3, 8, 11, 13, 15, 19, 20, 21, 22, 24, 31, 32, 36, 39, 43, 45, and 46 as follow:

3. (Amended) The medical device as recited in Clam 49, wherein said fixation agent comprises a bonding agent, and said device further comprising at least one opening for dispensing said bonding agent into the patient's body.

8. (Amended) A medical device comprising a shaft having a distal end, a proximal end, a localization wire, and a longitudinal axis, the device being adapted for placement of said distal end into a patient's body at a desired location, said medical device having a fixation agent disposed on said distal end, the fixation agent being adapted for affixing the distal end of said medical device at said desired location, further comprising a catheter having a lumen through which said localization wire is introduced into the patient's body.

11. (Amended) The medical device as recited in Claim 3, wherein said shaft comprises an outer wall formed from a coil of material, said coil being utilized to create an interstice which comprises said at least one opening for dispensing said bonding agent.

13. (Amended) The medical device as recited in Claim 3 comprising a surgical instrument, wherein said surgical instrument comprises a tissue acquisition device having a longitudinal axis about which said device is rotatable and comprises: a

cutting element disposed on said tube for cutting surrounding tissue; and a bushing disposed on said shaft which is rotatable relative to said shaft; wherein the bonding agent dispensed through said at least one opening affixes said bushing to surrounding tissue, so that the instrument is secured in a desired location without preventing rotational movement thereof.

15. (Amended) The medical device as recited in Claim 50, wherein said mechanical fixation agent comprises a Mallicot structure.

19. (Amended) The medical device as recited in Claim 50, wherein said mechanical fixation agent comprises a rolled stent and an axially movable sleeve, wherein when said sleeve is moved proximally the stent is exposed and unrolls to engage surrounding tissue and affix the distal end of the medical device.

20. (Amended) The medical device as recited in Claim 50, wherein said mechanical fixation agent comprises a radially expandable and retractable basket.

21. (Amended) The medical device as recited in Claim 49, wherein said fixation agent comprises an electrosurgical element disposed on the shaft distal end, which coagulates tissue surrounding the shaft distal end and thereby causes said tissue to be affixed to the shaft distal end.

22. (Amended) The medical device as recited in Claim 49, wherein said fixation agent comprises an electrical heating element disposed on the shaft distal end, which cauterizes tissue surrounding the shaft distal end and thereby causes said tissue to be affixed to the shaft distal end.

24. (Amended) The tissue acquisition instrument as recited in Claim 51, wherein said structure comprises comprising a lumen containing a bonding agent and at least one opening disposed at said distal end for dispensing said bonding agent to surrounding tissue.

31. (Amended) The tissue acquisition instrument as recited in Claim 51, wherein said mechanical fixation element comprises a Mallicot structure.

32. (Amended) The tissue acquisition instrument as recited in Claim 51, wherein said mechanical fixation element comprises a hinged linkage.

36. (Amended) The tissue acquisition instrument as recited in Claim 51, wherein said mechanical fixation element comprises a radially expandable and retractable basket.

39. (Amended) The tissue acquisition instrument as recited in Claim 51, wherein said instrument is rotatable about said longitudinal axis, said instrument further comprising: a bushing disposed on said instrument which is rotatable relative to said instrument; wherein said structure comprises an electrosurgical element disposed on said bushing, wherein when said electrosurgical element is energized, the surrounding tissue is coagulated and bonds to said bushing, so that the instrument is secured in a desired location without preventing rotational movement thereof.

43. (Amended) The method as recited in Claim 60, wherein the step of affixing the distal end of the instrument is performed by dispensing a bonding agent from said distal end into surrounding tissue.

45. (Amended) The method as recited in Claim 60, wherein the step of affixing the distal end of the instrument is performed by activating an electrosurgical element and operating it to coagulate tissue surrounding the distal end of the instrument, to an extent that the tissue bonds to the instrument distal end.

46. (Amended) The method as recited in Claim 60, wherein the step of affixing the distal end of the instrument is performed by activating an electrical heating element and operating it to cauterize tissue surrounding the distal end of the instrument, to an extent that the tissue bonds to the instrument distal end.

Please add the following new claims:

49. A medical device comprising a shaft having a distal end, a proximal end, and a longitudinal axis, the device being adapted for placement of said distal end into a patient's body at a desired location, said medical device having a fixation agent selected from the group consisting of a bonding agent, an electrical heating agent, an electrosurgical coagulating agent, an electrosurgical cauterizing agent, and combinations thereof, the fixation agent being configured for affixing the distal end of said medical device at said desired location.

50. A medical device comprising a shaft having a distal end, a proximal end, and a longitudinal axis, the device being configured for placement of said distal end into a patient's body at a desired location, said medical device having a mechanical fixation agent selected from the group consisting of a Mallicot structure, a stent, a sleeve, hinged structure, a basket, a wire, an anchor, and combinations thereof, said fixation agent being actuatable to extend outwardly into tissue surrounding the distal end of said

device to engage said tissue and to thereby anchor the distal end of the device at said desired location disposed on said distal end, the mechanical fixation agent being configured for affixing the distal end of said medical device at said desired location.

51. A tissue acquisition instrument for retrieving body tissue, having a longitudinal axis and comprising: a distal end adapted for entry into a patient's body; a cutting element disposed on said instrument for cutting surrounding tissue; and structure selected from the group consisting of a bonding element, a mechanical fixation element, an electrosurgical element, an electrical heating element, and combinations thereof, said structure being disposed on said distal end for securing said tissue acquisition instrument at a predetermined desired location, in order to insure that the tissue acquisition instrument remains in place during a tissue acquisition procedure so that a tissue specimen is properly acquired.

52. The tissue acquisition instrument as recited in Claim 31, wherein said tissue specimen has a transverse dimension and said Mallicot structure is configured to have a transverse dimension smaller than the transverse dimension of the tissue specimen.

53. The tissue acquisition instrument as recited in Claim 32, wherein said tissue specimen has a transverse dimension and said hinged linkage is configured to have a transverse dimension smaller than the transverse dimension of the tissue specimen.

54. The tissue acquisition instrument as recited in Claim 36, wherein said tissue specimen has a transverse dimension and said radially expandable and

retractable basket is configured to have a transverse dimension smaller than the transverse dimension of the tissue specimen.

55. The tissue acquisition instrument as recited in Claim 31, wherein said cutting element has a transverse dimension and said Mallicot structure is configured to have a transverse dimension smaller than the transverse dimension of the cutting element.

56. The tissue acquisition instrument as recited in Claim 32, wherein said cutting element has a transverse dimension and said hinged linkage is configured to have a transverse dimension smaller than the transverse dimension of the cutting element.

57. The tissue acquisition instrument as recited in Claim 36, wherein said cutting element has a transverse dimension and said radially expandable and retractable basket is configured to have a transverse dimension smaller than the transverse dimension of the cutting element.

58. A method for performing a tissue acquisition procedure using a tissue acquisition instrument having a distal end, a proximal end, a longitudinal axis, and a cutting element, the method comprising the steps of:

a) placing the distal end of the instrument in a patient's body, so that the distal end is disposed in a desired tissue location;

b) affixing the distal end of the instrument to said desired tissue location by performing a step selected from the group consisting of dispensing a

bonding agent from said distal end into surrounding tissue, activating an electrosurgical element, activating an electrical heating element, and combinations thereof.

59. The medical device of claim 49, wherein said fixation agent comprises a bonding agent selected from the group consisting of adhesives, solvents, and combinations thereof.

60. The method of claim 43, wherein said bonding agent is selected from the group consisting of adhesives, solvents, and combinations thereof.

REMARKS

Entry of the above amendments is respectfully requested. With the amendments, the specification reflects the priority of the application and claims 3-11, 13, 15, 19-22, 24-29, 31, 32, 35, 36, 39, 40, 43, 45, 46 are pending. No new matter is introduced by way of the amendments, which find support throughout the specification, at for example, page 11 line 26 to page 12 line 1, pages 15 –17 and Figs. 13-15.

Applicants wish to bring to the attention of the Patent Office the references listed on the attached PTO-1449 form and request that they be considered by the Examiner. Each of the references cited on the attached was previously cited by or submitted to the PTO in prior application Serial No. 09/146,185, filed September 1, 1998, therefore no copies are enclosed.

Consideration and early notification of allowance of the pending claims is earnestly requested.

Respectfully submitted,

By: _____

James A. Fox
Attorney for Applicants
Registration No. 38,455

Coudert Brothers LLP
600 Beach Street, 3rd Floor
San Francisco, CA 94109-1312
Telephone: (415) 409-2900
Facsimile: (415) 409-7400
Direct Dial: (650) 470-2934

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MARKED-UP VERSION TO SHOW CHANGES MADE

(Deleted words are [bracketed] and added words are underlined.)

3. (Amended) The medical device as recited in Clam [1] 49, wherein said fixation agent comprises a bonding agent, and said device further comprising at least one opening for dispensing said bonding agent into the patient's body.

8. (Amended) [The medical device as recited in Claim 2, wherein said medical device comprises a catheter, the] A medical device comprising a shaft having a distal end, a proximal end, a localization wire, and a longitudinal axis, the device being adapted for placement of said distal end into a patient's body at a desired location, said medical device having a fixation agent disposed on said distal end, the fixation agent being adapted for affixing the distal end of said medical device at said desired location, further comprising a catheter having a lumen through which said localization wire is introduced into the patient's body.

11. (Amended) The medical device as recited in Claim 3 [ )], wherein said [tube] shaft comprises an outer wall formed from a coil of material, said coil being utilized to create an interstice which comprises said at least one opening for dispensing said bonding agent.

13. (Amended) The medical device as recited in Claim [12] 3 comprising a surgical instrument, wherein said surgical instrument comprises a tissue acquisition device having a longitudinal axis about which said device is rotatable and comprises: a cutting element disposed on said tube for cutting surrounding tissue; and a bushing disposed on said [tube] shaft which is rotatable relative to said [tube] shaft; wherein the

bonding agent dispensed through said at least one opening affixes said bushing to surrounding tissue, so that the instrument is secured in a desired location without preventing rotational movement thereof.

15. (Amended) The medical device as recited in Claim [14] 50, wherein said mechanical fixation agent comprises a Mallicot structure.

19. (Amended) The medical device as recited in Claim [14] 50, wherein said mechanical fixation agent comprises a rolled stent and an axially movable sleeve, wherein when said sleeve is moved proximally the stent is exposed and unrolls to engage surrounding tissue and affix the distal end of the medical device.

20. (Amended) The medical device as recited in Claim [14] 50, wherein said mechanical fixation agent comprises a radially expandable and retractable basket.

21. (Amended) The medical device as recited in Claim [1] 49, wherein said fixation agent comprises an electrosurgical element disposed on the [tube] shaft distal end, which coagulates tissue surrounding the [tube] shaft distal end and thereby causes said tissue to be affixed to the [tube] shaft distal end.

22. (Amended) The medical device as recited in Claim [1] 49, wherein said fixation agent comprises an electrical heating element disposed on the [tube] shaft distal end, which cauterizes tissue surrounding the [tube] shaft distal end and thereby causes said tissue to be affixed to the [tube] shaft distal end.

24. (Amended) The tissue acquisition instrument as recited in Claim [23] 51, wherein said structure comprises comprising a lumen containing a bonding agent and at

least one opening disposed at said distal end for dispensing said bonding agent to surrounding tissue.

31. (Amended) The tissue acquisition instrument as recited in Claim [30] 51, wherein said mechanical fixation [agent] element comprises a Mallicot structure.

32. (Amended) The tissue acquisition instrument as recited in Claim [31] 51, wherein said mechanical fixation [agent] element comprises a hinged linkage.

36. (Amended) The tissue acquisition instrument as recited in Claim [31] 51, wherein said mechanical fixation [agent] element comprises a radially expandable and retractable basket.

39. (Amended) The tissue acquisition instrument as recited in Claim [23] 51, wherein said instrument is rotatable about said longitudinal axis, said instrument further comprising: a bushing disposed on said instrument which is rotatable relative to said instrument; wherein said structure comprises an electrosurgical element disposed on said bushing, wherein when said electrosurgical element is energized, the surrounding tissue is coagulated and bonds to said bushing, so that the instrument is secured in a desired location without preventing rotational movement thereof.

43. (Amended) The method as recited in Claim [42] 60, wherein the step of affixing the distal end of the instrument is performed by dispensing a bonding agent from said distal end into surrounding tissue.

45. (Amended) The method as recited in Claim [42] 60, wherein the step of affixing the distal end of the instrument is performed by activating an electrosurgical

element and operating it to coagulate tissue surrounding the distal end of the instrument, to an extent that the tissue bonds to the instrument distal end.

46. (Amended) The method as recited in Claim [42] 60, wherein the step of affixing the distal end of the instrument is performed by activating an electrical heating element and operating it to cauterize tissue surrounding the distal end of the instrument, to an extent that the tissue bonds to the instrument distal end.